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Via E-Mail

The Honorable Dennis M. Cavanaugh
Special Master
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Re: *United States ex rel. Simpson v. Bayer Pharmaceutical Corp., et al.*
Civil Action No. 2:05-cv-03895 (JMZ) (JAD)

Dear Judge Cavanaugh:

The United States respectfully submits this letter brief in opposition to Bayer's Motion to Compel Production of Documents From the United States Government dated March 25, 2020 (Bayer Mot. Compel). The United States respectfully cross-moves to quash Bayer's subpoenas in their entirety pursuant to Fed. R. Civ. P. 45(d)(3).

Bayer has propounded five burdensome subpoenas under Fed. R. Civ. P. 45 to five separate governmental agencies, four of which play no role in CMS's automated processing and payment of the Medicare claims at issue in this case. Each of Bayer's subpoenas is vastly overbroad, unduly burdensome, and disproportional to the needs of the case. None of the subpoenas seek information relevant to the Government's payment decision, which goes to the heart of the materiality inquiry. More specifically, they do not seek information about what the Government "would have done" if it had "actual knowledge that certain requirements were violated." *United States ex rel. Simpson v. Bayer*, 376 F. Supp. 3d 392, 415 (D.N.J. 2019) (quoting *Universal Health Services, Inc. v. United States ex rel. Escobar*, 136 S. Ct. 1989, 2003-04 (2016) (*Escobar*)).

Each Government agency responded to their respective subpoenas with timely written objections, as required under Fed. R. Civ. P. 45(d)(2)(B). Notwithstanding their objections, CMS and FDA conferred with Bayer's counsel on multiple occasions, conducted extensive searches among their respective agency components and contractors, and produced several thousands of pages of responsive documents in accordance with Bayer's stated priorities. CMS also provided

links to additional documents on the CMS website and referred Bayer to the very information it now contends is missing, including operational documents reflecting Medicare's processes for the payment or denial of claims, Medicare coverage and payment rules regarding unapproved or off-label uses of drugs, and manuals on how Medicare handles cases of suspected fraud, waste and abuse, *all of which are publicly available*.

During the extensive meet and confer process, Bayer refused to narrow or take any of its requests off the table, and also refused to take any reasonable steps to avoid imposing undue burden or expense on the Government, as required by Fed. R. Civ. P. 45(d)(1). Bayer rejected the Government's suggestion that it opt for electronic claims data, which is far "more convenient, less burdensome, and less expensive," and insisted on the burdensome production of other records that have no bearing on the materiality inquiry. Bayer dismissed the Government's concerns over the breadth, burden, and expense of its discovery by suggesting that the Government could either opt to dismiss the relator's complaint under the False Claims Act, 31 U.S.C. § 3730(c)(2)(A), or enter into an inaccurate "stipulation" for Bayer's own litigation advantage. And now Bayer has filed a motion to compel that, like its subpoenas, lacks any clear focus or direction as to what relevant, responsive documents it believes exist but that have not been produced.

Because the Government has produced and/or provided links to thousands of pages of documents and offered to produce electronic claims data that is more convenient, less burdensome, and less expensive to produce, it has more than complied with its obligations under Fed. R. Civ. P. 45. Because Bayer's vastly overbroad subpoenas seek information that is irrelevant and disproportional to the needs of this case, the United States respectfully requests that the Court deny Bayer's motion to compel and quash Bayer's subpoenas in their entirety.

FACTUAL AND PROCEDURAL BACKGROUND

A. The Supreme Court's Decision in *Escobar* and this Court's April 23, 2019 Decision Regarding the Materiality Standard Under the False Claims Act

On October 5, 2018, Bayer filed a motion for partial summary judgment in this case, arguing that Medicare's Diagnostic Related Group (DRG) or bundled system for the payment of hospital claims precluded a pharmaceutical company such as Bayer from being held liable under the FCA for paying kickbacks or for marketing pharmaceutical products for unapproved uses. Bayer contended that because any such violations would not increase the amount the Government paid under Medicare's DRG system of payment, those violations could not be material under the FCA as a matter of law.

On April 23, 2019, this Court issued its decision rejecting Bayer's argument that Medicare's DRG fixed fee payment system precluded relator from proving that the violations alleged in the relator's complaint were material to the Government's payment decision. *Bayer*, 376 F. Supp. 3d at 392. In its decision, this Court followed the materiality analysis set forth by the Supreme Court in *Escobar*.

The materiality analysis under *Escobar* examines whether compliance with a particular statute or requirement actually matters to the Government or is otherwise "minor or insubstantial." *Escobar*, 136 S. Ct. at 2003. The materiality analysis requires an assessment of several non-dispositive factors, of which no single factor is determinative. *Escobar*, 136 S. Ct. at 2001 (citing *Matrixx Initiatives, Inc. v. Siracusano*, 563 U.S. 27, 39 (2011)). The *Escobar* factors are: (1) whether the applicable requirement is a condition of payment; (2) whether the requirement allegedly violated goes to the "essence of the bargain;" (3) whether the violation is significant or trivial, and (4) what actions the government takes when it gains "actual knowledge that certain requirements were violated." *Escobar*, 136 S. Ct. at 2003.

The requirements at issue in this case are the Anti-kickback Statute (AKS)[1] and the "reasonable and necessary" requirement set forth in 42 U.S.C. 1396y(a)(1)(A). Both are plainly material to the Government's payment decision. This Court has declared that "both the AKS and the 'reasonable and necessary' requirement in 42 U.S.C. § 1396y(a)(1)(A) are designated as conditions of payment under Medicare." *Bayer*, 376 F. Supp. 2d at 414.

These requirements also go to the essence of the bargain, and are significant and not trivial. This Court determined that "in the context of an underlying AKS violation '[t]he Government does not get what it bargained for when a defendant is paid . . . for services tainted by a kickback.'" *See id.* at 411 (quoting *United States ex rel. Greenfield v. Medco Health Solutions*, 880 F. 3d 89, 97 (3d Cir. 2018)); *United States ex rel. Capshaw v. White*, 2018 WL 6068806, at *4 (N.D. Tex. Nov. 20, 2018) ("AKS violations are not the 'garden-variety breaches of contract or regulatory violations'". . . but are "serious, consequential, felony transgressions of law that the Government actively enforces."); *see also* 42 C.F.R. § 1001.951 (providing for the exclusion from federal healthcare programs any individual or entity that violates the AKS).

Similarly, given the explicit statutory prohibition against Medicare payment for "items or services which ... are not *reasonable and necessary* for the diagnosis or treatment of illness or injury," 42 U.S.C. 1395y(a)(1)(A), it cannot credibly be disputed that the Government does not get what it bargained for when it pays for medically unnecessary Medicare claims. The "reasonable and necessary" requirement lies at the very heart of the Medicare program and is the primary consideration determining coverage and payment under Medicare. *See Heckler v. Ringer*, 466 U.S. 602, 605 (1984) (recognizing that the Medicare statute "precludes reimbursement for any 'items or services ... which are not reasonable and necessary for the diagnosis or treatment of illness or injury.'").

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[1] Given the unique importance of the AKS, the widespread acknowledgement by courts that compliance with the AKS affects federal health care reimbursement decisions, and the enactment of Section 1320a-7b(g), several courts have held that violations of the AKS are material under the FCA *as a matter of law*. *See, e.g.*, *Guilfoile v. Shields*, 913 F.3d 178, 190 (1st Cir. 2019) (reading Section 1320a-7(b)(g) as "obviating the need for a plaintiff to plead materiality"); *United States ex rel. Lutz v. Berkely Heartlab*, 2017 WL 6015574, at *2 (holding that AKS compliance is *per se* material); *United States ex rel. Wood v. Allergan, Inc.*, 246 F. Supp. 3d 772, 818 (S.D.N.Y. 2017) (concluding that compliance with the AKS is a 'material' condition of payment), *rev'd and remanded on other grounds*, 899 F.3d 163 (2d Cir. 2018).

Finally, the Government routinely takes action to recover overpayments, whether through error or fraud. More specifically, the Government frequently pursues FCA cases arising from violations of the AKS or the "reasonable and necessary" requirement as it relates to off-label uses of drugs, sometimes years after the claims themselves have been paid, and such cases are a matter of public record.

Even though all of the *Escobar* factors weigh strongly in favor of a determination of materiality, this Court left Bayer with a narrow opening on the fourth, Government action factor, to offer "proof that 'the Government pays a particular claim in full despite actual knowledge that certain requirements were violated,' or evidence that 'the Government regularly pays a particular type of claim in full despite actual knowledge that certain requirements were violated, and has signaled no change in its position.'" *Bayer*, 376 F. Supp. 2d at 415 (quoting *Escobar*, 136 S. Ct. at 2003-04).

Bayer's motion to compel demonstrates a fundamental misunderstanding of both *Escobar* and this Court's decision on this issue. In its demand for broad discovery from the Government, Bayer repeatedly claims that it is entitled to probe into whether the Government "has ever denied payment" for claims arising from kickbacks or off-label promotion. But that is the wrong question for two reasons. First, the issue of Government action is relevant to the extent it shows what the Government does when it knows of the fraud. The issue of whether the Government has paid or denied claims resulting from illegal conduct when it did not actually know about the fraud is of no probative value whatsoever. Second, the Government action factor is not limited to what the Government does at the time a claim is submitted and processed for payment, which occurs through an automated system, but rather it is evaluated based on the full panoply of options available to the Government to address payments due to errors or fraud, including criminal, civil, and administrative actions to recover funds.

By allowing Bayer the opportunity to offer proof on the Government action factor, neither *Escobar* nor this Court authorized boundless fishing expeditions for information across multiple governmental agencies or into every "facet of the Medicare Program." *See* ECF No. 363-2, Rule 45 Subpoena to CMS dated March 13, 2019 ("CMS Subpoena), Request Nos. 1, 8, 9, 14, 15. Nor did the Court authorize burdensome and unverifiable inquiries such as whether the Medicare program has ever denied payment under proffered circumstances. Bayer Mot. Compel at 6. These types of inquiries reveal nothing about the importance the Government places on compliance with a particular statute or requirement. Rather, to the extent any discovery as to Government action is relevant, it must be limited to how the Government acts when it has "actual knowledge" of the violations at issue in the case.

LEGAL STANDARD

As this Court has frequently recognized, "the burden remains on the party seeking discovery to 'show that the information sought is relevant to the subject matter of the action and may lead to admissible evidence.'" Order and Opinion of the Special Master (March 26, 2020) at 8 ("Order") (citing *Caver v. City of Trenton*, 192 F.R.D. 154, 159 (D.N.J. 2000)). Although the scope of discovery under the Federal Rules is broad, it "is not unlimited and may be

circumscribed." *Bayer AG v. Betachem, Inc.*, 173 F.3d 188, 191 (3d Cir. 1999). In addition, "the court must limit the . . . extent of discovery otherwise allowed . . . if it determines that: (i) the discovery sought is unreasonably cumulative or duplicative, or can be obtained from some other source that is more convenient, less burdensome, or less expensive." Fed. R. Civ. P. 26(b)(2)(C)(i).

Furthermore, discovery does not extend to information that is publicly available and equally accessible to all parties. *See In re Ampal-American Israel Corp.*, No. 12-13689 (SMB, 2019 WL 3756728, at *7 (S.D.N.Y. 2019) (citing *SEC v. Samuel H. Sloan & Co.*, 369 F. Supp. 994, 995-96 (S.D.N.Y. 1973) ("It is well-established that discovery need not be required of documents of public record which are equally accessible to all parties.").

Rule 45(d) provides additional protections to non-parties. In particular, "a party or attorney responsible for issuing a subpoena *must take reasonable steps* to avoid imposing undue burden or expense on a person subject to the subpoena." Fed. R. Civ. P. 45(d)(1) (emphasis added). The court "must enforce this duty and impose an appropriate sanction . . . on a party or attorney who fails to comply." Fed. R. Civ. P. 45(d)(1); *In re Modern Plastics Corp.*, 890 F.3d 244 (6th Cir. 2018) (affirming the imposition of sanction on a party that failed to comply with its duty under Rule 45(d)(1)). While "[b]are allegations of burden will not suffice where the information requested is 'entirely relevant to' the party's claims and the subpoena is 'appropriately limited," a court need not "require documentary evidence of the specific cost or burden of production where a subpoena is facially overbroad or the information sought is irrelevant, privileged, or more readily obtainable from other sources." *Nye v. Ingersoll Rand Co.*, Civ. No. 08-3481 (DRD), 2011 WL 253957, at *6 (D.N.J. Jan. 25, 2011).

Any court order for production or inspection must also protect the non-party "from significant expenses resulting from compliance." Fed. R. Civ. P. 45(d)(2)(B)(ii). Under this rule, fee shifting to protect a non-party from significant expense imposed by a subpoena is mandatory. *R.J. Reynolds Tobacco v. Philip Morris, Inc.*, 29 F. App'x 880, 882 (3d Cir. 2002) ("[s]ignificant expenses must be borne by the party seeking discovery"); *Linder v. Calero–Portocarrero*, 251 F.3d 178, 182 (D.C. Cir. 2001) ("Rule 45 requires [mandatory fee shifting] – the district court 'shall protect' a non-party from 'significant expense.'"); *Legal Voice v. Stormans Inc.*, 738 F.3d 1178, 1184 (9th Cir. 2013) ("hold[ing] that Rule 45(d)(2)(B)(ii) requires the district court to shift a non-party's costs of compliance with a subpoena, if those costs are significant").

Finally, "discovery under Rules 26 and 45 must properly accommodate 'the government's serious and legitimate concern that its employee resources not be commandeered into service by private litigants to the detriment of the smooth functioning of government operations." *Watts v. SEC*, 482 F.3d 501, 509 (D.C. Cir. 2007) (quoting *Exxon Shipping Co. v. Dep't of Interior*, 34 F.3d 774, 776 (9th Cir. 1994)).

ARGUMENT

I. The Government's Extensive Efforts to Provide Responsive Information to Bayer

Each of the five subpoenas Bayer has propounded on the Government is a fishing expedition for irrelevant documents having no bearing on the materiality inquiry – Bayer's claimed need for discovery. The overbreadth, undue burden, and disproportionality is obvious from the face of the subpoenas. Four of the five agencies subpoenaed by Bayer (FDA, DOJ, VA and DOD) play no role in CMS's automated processing and payment of the Medicare claims at issue in this case, and, therefore, Bayer's subpoenas to those agencies are facially irrelevant.

Each of Bayer's subpoenas seek documents and information spanning a twenty-five year time-frame (January 1, 1996 to the present) even though the Court has determined that the relevant time period for this case is August 1999 through 2006. None of Bayer's subpoenas are limited to the specific claims or types of claims at issue in this case. None of the subpoenas are limited to the specific violations at issue in this case, the AKS or the "reasonable and necessary" requirement. And significantly, none of the subpoenas seek information relevant to an assessment of the Government's payment decision, namely what the Government "would have done" if it had "actual knowledge that [these] requirements were violated." *Bayer*, 376 F. Supp. 3d at 415.

Despite the overbreadth, undue burden and irrelevance of Bayer's subpoenas to the materiality inquiry, Bayer's purported need for discovery, each agency has responded with written objections, as required under Fed. R. Civ. P. 45(d)(2)(B).[2] Furthermore, and as detailed below, despite those objections, the Government conferred extensively with Bayer and produced or provided links to as much responsive information as possible.

A. CMS Has Conducted Extensive Searches And Produced or Provided Links to Thousands of Pages of Documents In Response to Bayer's Overbroad Subpoena

Bayer's subpoena to CMS contained thirty broad and burdensome requests, almost none of which sought relevant information. Rather, several of Bayer's requests are so broadly worded, they could encompass virtually every document generated by CMS in administering the Medicare Program over a twenty-five year period. *See* ECF No. 363-2, CMS Subpoena Request Nos. 1, 8, 9, 14, 15 (demanding documents "in any way related" to "claims received under any facet of the Medicare program"). Other requests are vague and incomprehensible, or difficult to translate into a searchable instruction. *See e.g.*, *id.* CMS Subpoena Request No. 7 (demanding documents on "whether and how CMS would deny a claim because a non-medical product used during a

[2] Each agency also objected to Bayer's subpoenas because they failed to comply with each agencies' respective *Touhy* regulations governing the request of documents when the United States is not a party to litigation. *See United States ex rel. Touhy v. Ragen*, 340 U.S. 462, 468-70 (1951) (upholding regulation prohibiting agency employees from releasing documents without consent of agency head). These regulations recognize that if private litigants such as Bayer could, upon demand, compel agencies to produce documents for litigation in which the United States is not a party, the agencies' resources would be diverted from their respective public missions.

procedure, *e.g.*, lightbulbs in the operating room or a patient's food, was obtained allegedly in violation of law"); CMS Subpoena Request Nos. 17, 19, 21, 23 (demanding documents on "why CMS decided to include or omit certain information" from various CMS forms, without identifying the information).

By letter dated March 25, 2019, CMS provided timely and written objections to Bayer's subpoena pursuant to Fed. R. Civ. P. 45(d)(2)(B). *See* ECF No. 363-3, Letter from L. Turner to J. Cohn dated March 25, 2019. Despite written objections to the scope, breadth, relevance and vagueness of Bayer's subpoena, CMS sought to cooperate with Bayer and produce responsive information without subjecting the agency to undue burden.

Contrary to Bayer's assertion that CMS has refused to cooperate, between April and December 2019, counsel for CMS conferred with Bayer's counsel on ten separate occasions, made nine separate productions consisting of thousands of pages of responsive documents, and provided links or referred Bayer to many more documents publicly available on the CMS website. Counsel for CMS provided Bayer with regular updates on the status of its productions (even sending weekly updates for a while) and discussed a range of issues, including prioritization, scope, specific productions, follow-up on those productions, the aged paper records, electronic claims data, and various other topics. *See, e.g.*, Compilation of meet and confer update emails from CMS counsel dated April 2019 through July 2019 (Exhibit G to Bayer Mot. Compel).

Based on those discussions, CMS spent countless hours searching for and producing, or providing links to, responsive documents from multiple components within CMS, Medicare Administrative Contractors ("MACs"), and Uniform Program Integrity Contractors ("UPICs"). CMS produced the following categories of documents in its nine productions:

- Medicare Part A and Part B claims processing flow charts;
- Current and historical versions of CMS forms 855, 1450, 1500, 2252-10, specifically requested by Bayer;
- Technical Direction Letters and Change Requests concerning revisions to those forms;
- Articles and other documents referring to kickbacks;
- Reason/remark codes;
- Historical versions of Chapter 22 of the Medicare Claims Processing Manual;
- Annual ethics training for CMS employees;
- National and local coverage determinations;
- Webpages referring to claims submission, fraud and abuse;
- Injection code instructions;
- Reason Code and Help Messages;
- Medical Review Work Instructions;
- Internal operating procedures addressing medical review procedures;
- Medicare and Medicaid DRG validation procedures;
- Coding validation procedures;
- Scanning Procedures and QA Review of Medical Decision Procedures;
- Part A and Part B reason code; and

- Medical Review database file that included Avelox.

See CMS Production Letters (attached as Exhibit 1).

In addition, CMS referred Bayer to a number of publicly available documents responsive to its specific requests, including Medicare statutes, regulations, National Coverage Determinations, Local Coverage Determinations, online manuals, program memoranda, and other guidance documents addressing the processing, coverage and payment of Medicare claims. *See* Letter from E. Heard to J. Perez dated October 16, 2019, at 3-6 (Exhibit I to Bayer Mot. Compel).[3] Examples of publicly available information responsive to Bayer's requests include a number of policy manuals, all of which are available on the CMS website. Embedded within the current version of each manual are links to earlier versions of these manuals dating back to 2003 and in some cases to 2000.

Title (Publication)	**Description**
Medicare Benefit Policy Manual (Pub. 100-02) https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/Internet-Only-Manuals-IOMs-Items/CMS012673	Describing in detail Medicare's coverage policies. Ch. 1 (Inpatient Hospital Services Covered Under Part A), § 30.3 (Drug and Biologicals) ("[u]se of the drug or biological [in the hospital] must be safe and effective and otherwise reasonable and necessary as specified in the Medicare Benefit Policy Manual, Chapter 15, "Covered Medical and Other Health Services, § 50")
	Ch. 15, § 50 ("drugs and biologicals are covered only if . . . [t]hey are reasonable and necessary for the diagnosis or treatment of the illness or injury for which they are administered according to accepted standards of medical practice")
	Ch. 15, § 50.2A (Medicare Administrative Contractors "must continue to apply the policy that not only the drug is medically reasonable and necessary for any individual claim, but also that the route of administration is medically reasonable and necessary")
	Ch. 15, § 50.4 ("Reasonableness and Necessity" regarding the use of drugs)
	Ch. 15, § 50.4.1 ("use of the drug or biological must be safe and effective and otherwise reasonable and necessary")
	Ch. 15, § 50.4.2 ("Unlabeled Use of Drug")

[3] Since 2003, CMS has published a series of manuals consolidating various program instructions into an electronic Web-based manual system for all users. All the manuals are available online and located at https://www.cms.hhs.gov/manuals. These manuals are a replica of CMS's official record copy and consist of program issuances, day-to-day operating instructions, policies, and procedures that are based on statutes, regulations, guidelines, models, and directives. CMS program components, providers, contractors, and other entities use these manuals to administer CMS programs.

	Ch. 15, § 50.4.3.3 ("[i]f a medication is determined not to be reasonable and necessary for the diagnosis or treatment of illness or injury according to these guidelines, the [Medicare Administrative Contractor] excludes the entire charge (i.e. for both the drug and its administration)."
	Ch. 16, § 10 ("No payment can be made under either the hospital insurance or supplementary medical insurance program for certain items and services, when the following conditions exist. . . .[n]ot reasonable and necessary").
Medicare National Coverage Determinations (NCD) Manual (Pub. 100-03) https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/Internet-Only-Manuals-IOMs-Items/CMS014961	Cataloging National Coverage Determinations and "describ[ing] whether specific medical items, services, treatment procedures, or technologies can be paid for under Medicare." It expressly states that "[d]ecisions that items/services are not covered are generally based on [42 U.S.C. § 1395y(a)(1)] (the 'not reasonable and necessary' exclusion) unless otherwise noted."
Medicare Claims Processing Manual (Pub. 100-04) https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/Internet-Only-Manuals-IOMs-Items/CMS018912	Describing in detail the process for billing and payment of Medicare claims. Chapter 3 – Describing in detail inpatient Hospital Billing, including General Inpatient Requirements; and Payment under Prospective Payment System (PPS) Diagnostic Related Groups (DRGs).
Medicare Program Integrity Manual (Pub. 100-08) https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/Internet-Only-Manuals-IOMs-Items/CMS019033	Describing in detail CMS's efforts to curb fraud, waste, and abuse in the Medicare Program. Ch. 4 (Program Integrity), § 4.2.1 Listing Examples of Medicare Fraud ("[s]oliciting, offering, or receiving a kickback, bribe, or rebate (e.g., paying for a referral of patients in exchange for the ordering of diagnostic tests and other services or medical equipment") Ch. 4 (Program Integrity), § 4.22.1 "Anti-Kickback Statute Implications"

Indeed, most if not all of the documents Bayer claims are missing, such as CMS's policies regarding coverage (payment or denial) under Medicare, Bayer Mot. Compel at 6, operational documents reflecting the processing of Medicare claims, Bayer Mot. Compel at 5, n. 5, or CMS's efforts to curb fraud, waste, and abuse in the Medicare program, Bayer Mot. Compel at 6-7, are publicly available to Bayer on the CMS website, within CMS's nine productions, or in electronic claims data that Bayer inexplicably refuses to request.

CMS also repeatedly offered Bayer electronic claims data. By letter dated October 16, 2019, CMS provided Bayer with a detailed update on the status of specific requests previously identified by Bayer (CMS Subpoena Request Nos. 3-15, 17, 19, 21, and 23). *See* Letter from E. Heard to J. Perez dated October 16, 2019 (Exhibit I to Bayer Mot. Compel). As part of that update,

CMS explained that an electronic data request was the best source of information for several of the requests, including CMS Request Nos. 5, 6, 10, 11, 12, 13, 14, and 15. *See id*. CMS advised Bayer that the relator had recently submitted a request to CMS for electronic claims data. In order to preserve the parties' resources and reduce the possibility of duplicative requests, CMS invited Bayer to confer with the relator on an agreed-upon set of parameters (hospitals and DRG codes by year) and an equitable apportionment of CMS's normal processing charge between Bayer and the relator. *See id*.

Bayer refused, claiming "it is impossible for us to definitively state what additional data we need from CMS." *See* Email from N. Chandran to L. Turner dated January 31, 2020 (attached as Exhibit 2). We do not think it is "impossible" for Bayer to make an informed decision about an electronic claims data request. Relator was able to identify specific hospitals and DRG codes. Bayer certainly knows the hospitals to which it sold Trasylol and need only identify (or agree with the relator's identification of) specific DRG codes. Having received the full payment from the relator for the normal processing charge, CMS is now in the process of furnishing electronic claims data to the relator.

By letter dated February 11, 2020, CMS also provided Bayer with a detailed explanation of its efforts to search for documents responsive to its subpoena. CMS explained that even though it viewed Bayer's discovery as irrelevant, "CMS and its contractors have conducted exhaustive searches for responsive records, produced thousands of pages of information, and offered to produce electronic claims data." *See* Letter from E. Heard to J. Cohn dated February 11, 2020, at 3 (attached as Exhibit M to Bayer Mot. Compel). CMS further explained that it had conducted "follow-up searches based on additional information provided by counsel" and "[i]n many cases, CMS and its contractors double and triple-checked to confirm they did not overlook any likely data sources." *Id*. CMS offered to consider searching for additional information if Bayer was "willing to identify a limited and discrete category of records within the relevant time period for the claims at issue in the litigation." *Id*. at 4. Bayer filed its motion to compel.

Finally, the Government wishes to address the issue of the other boxes of paper records not covered by the Government's October 3, 2019 motion to quash. As the Court is aware, Bayer's subpoena to CMS seriously disrupted the planned disposal of aged paper records dated from 1996 to 1999.

There remains approximately 16,000 boxes of unknown date range[4] and approximately 800,000 boxes consisting of over two billion pages of aged paper records dating from 2000 to 2006. *See* Third Supplemental Declaration of Chris Klots ("Third Klots Suppl. Decl.") dated May 8, 2020, ¶¶ 3-4, 10 (attached as Exhibit 10). These boxes are stored at more than twelve archival storage facilities around the country. *Id*. at ¶ 3. These aged paper boxes contain the same categories of information as the aged paper records from 1996 to 1999, lack payment decisions,

[4] CMS originally estimated that there were 44,000 boxes of unknown date range held by one particular Medicare Administrative Contractor (MAC). *See* ECF No. 363-4, July 16, 2019, Memorandum from Chris Klots ("Klots Memorandum") at 7. Based on updated information, that figure is now down to 16,000 boxes. *See* Third Klots Suppl. Decl. ¶¶ 9-10.

and thus have no relevance to this case. *See id*. ¶ 8. Accordingly, providing access to these irrelevant aged paper records for inspection to Bayer is plainly disproportional to the needs of the case. Moreover, given the current travel restrictions and current staffing levels at the archival storage facilities and MACs due to the ongoing national emergency arising from the COVID-19 outbreak in the United States, these aged paper records are not accessible. *See id*. ¶ 12. Finally, to the extent Bayer seeks information regarding the Government's "conduct regarding the payment of claims," an appropriately framed and narrowly targeted request for electronic claims data is far "more convenient, less burdensome, and less expensive" to produce. *See* Fed. R. Civ. P. 26(b)(2)(C)(i).

At this time, the Government is not seeking cost shifting as to any expenses thus far incurred by CMS with respect to the remaining 16,000 boxes of unknown date range, or the 2000 to 2006 aged paper records. If, however, Bayer requests or the Court orders that these boxes of aged paper records be retained by CMS or made available for Bayer's inspection at some future date, the United States requests that, for the reasons set forth in the Government's cost shifting request as to the 1996 to 1999 records (ECF-Nos. 373 and 374), the Court shift to Bayer under Fed. R. Civ. P. 45(d)(1) or 45(d)(2)(B)(ii) a portion of the significant expense resulting from compliance such that Bayer bears "at least enough of the expense to render the remainder 'non-significant.'" *Linder v. Calero–Portocarrero*, 251 F.3d 178, 182 (D.C. Cir. 2001); *R.J. Reynolds Tobacco v. Philip Morris, Inc.*, 29 F. App'x 880, 882 (3d Cir. 2002).

In sum, the undue burden and expense posed by the breadth of Bayer's subpoena is not limited to the aged paper records. CMS has searched for records among multiple components with CMS, multiple MACs and UPICs, based on Bayer's unreasonably broad, vague, and, in certain instances, incomprehensible requests. CMS has conducted extensive searches of locations that are reasonably accessible, and in some cases, double and triple-checked with its contractors for further responsive documents. In light of CMS's extensive record of compliance, including nine-separate productions of documents consisting of thousands of pages of documents, the public availability of significant amounts of additional information, Bayer's refusal to seek more convenient, less burdensome, and less expensive discovery under Rule 26(b)(2)(C)(i) in the form of targeted electronic claims data, and Bayer's failure to identify any discrete category of missing information, the Government respectfully requests that Bayer's motion to compel be denied and its subpoena to CMS quashed in its entirety.

B. FDA Has Conducted Extensive Searches And Produced or Provided Links to Thousands of Pages of Documents In Response to Bayer's Overbroad Subpoena

Bayer's subpoena to FDA contained twenty broad and burdensome requests, spanning a twenty-five year period, from 1996 to the present. As Bayer well knows, the FDA does not make payment decisions on Medicare claims submitted to CMS. Not a single request to FDA has any bearing on the Government action factor—what the Government "would have done" if it had "actual knowledge that certain requirements were violated." Nor has Bayer explained how any of its requests to FDA have any bearing on the materiality issue.

Many of Bayer's requests to FDA seek information about Trasylol or Avelox likely to be in Bayer's own possession, such as documents relating to FDA's approval of Trasylol and Avelox for distribution in the United States or documents relating to Bayer's removal of Trasylol from the market. *See e.g.*, Rule 45 Subpoena to FDA dated March 13, 2019 ("FDA Subpoena") (Exhibit C to Bayer Mot. Compel), Request Nos. 1-4, 6-8. Other requests used vague and ambiguous terms, such as "allegedly harmful drugs" or sought documents regarding FDA actions because of "alleged" kickbacks or "allegedly unreasonable or unnecessary use of" Trasylol, Avelox, "or any other drug."[5] *See* FDA Subpoena Request Nos. 9-2, 14-18.

Pursuant to Fed. R. Civ. P. 45(d)(2)(B), FDA submitted timely objections to Bayer's subpoena on several grounds, including that the subpoena was overbroad and unduly burdensome. *See* Letter from A. Zamora (FDA) to J. Cohn dated March 28, 2019 (attached as Exhibit 3).[6] FDA nevertheless expressed its willingness to work with Bayer to produce responsive documents, but encouraged Bayer to "to narrow the scope of your requests and prioritize the types of documents that you are requesting." *See id*. Between March and November 2019, FDA had numerous calls and communications with Bayer regarding its subpoena. Nevertheless, Bayer refused to narrow its subpoena or take any requests off the table.

Contrary to Bayer's contention, FDA made three separate productions consisting of several thousands of pages of documents in response to FDA Request Nos. 1-3, 6-8, and 19-20. *See* FDA Production Letter/Emails dated April 14, 2019, June 4, 2019, and July 18, 2019 (attached as Exhibit 4). By email dated October 17, 2019, FDA advised Bayer that it "did not locate any records that are responsive to request 5 or requests 9-13. For requests 14-18, we think it would be helpful to have a call to discuss the scope of these requests."[7] *See* Email from L. DiPaola (FDA) to N. Chandran dated October 17, 2019 (attached as Exhibit 5). Following a subsequent conference call with Bayer's counsel on October 31, 2019, FDA conducted a further search of several components within FDA's Center for Drug Evaluation and Research, where responsive records (if any) were likely to be located. *See id.* at 1 (November 20, 2019 Email from L. DiPaola to N.

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[5] Kickbacks and references to "unreasonable and necessary" use of drugs are not ordinarily terms used by the FDA in fulfilling its public service mission.

[6] As Bayer well knows, FDA is prohibited from producing trade secret information, under 21 U.S.C. § 331(j). In addition, the Trade Secrets Act, 18 U.S.C. § 1905, prohibits the release of trade secret and confidential commercial information ("CCI") unless otherwise authorized by law. Further, FDA regulations provide that trade secret and CCI are not available for public disclosure. See 21 C.F.R. § 20.61. Accordingly, FDA is unable to produce any responsive information that would reveal trade secret and/or confidential research, development, or commercial information, and each document must be painstakingly reviewed and redacted as necessary. *See also* Fed. R. Civ. P. 45(d)(3)(B)(i).

[7] FDA's search did not include publicly available documents on the FDA website that may be potentially responsive to Bayer's requests. For example, FDA guidances, which reflect FDA's views on a particular subject, are available at the following link: https://www.fda.gov/drugs/guidance-compliance-regulatory-information/guidances-drugs. FDA "enforcement activities" including a list of Warning Letters issued by the agency are available at the following link: https://www.fda.gov/drugs/guidance-compliance-regulatory-information/enforcement-activities-fda. It is not necessary for the Government to produce documents that are publicly and available to Bayer through basic internet research. *See In re Ampal-American Israel Corp.*, 2019 WL 3756728 (S.D.N.Y. 2019).

Chandran). The FDA listed for Bayer all of the different components within FDA that had searched for responsive documents. *Id*. Following that search, FDA confirmed in writing to Bayer that it "could not locate any records responsive to request 5 or requests 9-13[.]" *Id*. The FDA further indicated that it had also conducted "a search of the HHS/Office of General Counsel/Food and Drug Division" but "did not locate any records that are responsive to requests 14-18." *Id*.

On June 4, 2019, FDA provided chronological lists, totaling 141 pages, of FDA and Bayer records in FDA's possession for Trasylol and Avelox.[8] *See* Exhibit 4, FDA Production Letter/Emails at 3 (Email from L. DiPaola to J. Cohn dated June 4, 2019). FDA provided the lists pursuant to a call with Bayer to facilitate continued discussions on scope and narrowing of requests. *Id*. Bayer never used the lists to request a single document or to clarify or narrow the scope of its requests.

Bayer's motion to compel with respect to FDA is meritless. Having requested documents covering a twenty-five year period, and having refused to waive any of its requests, it is deeply ironic that Bayer now complains about receiving documents "irrelevant to Bayer's document requests" or "outside the time period that the *Government contends* is relevant to this litigation." Bayer Mot. Compel at 9 (emphasis added). While the Government agrees that the relevant time period is August 1999 through 2006, Bayer has only itself to blame for propounding such a temporally overbroad subpoena. Although Bayer agreed to prioritize the production of some requests, it never waived nor relieved the FDA of the burden of complying with the full scope or temporal range of its requests. To underscore this point, Bayer emphasized from the very outset that "we are not waiving our requests." *See* Email from K. Johnson (Bayer) to L. DiPaola, dated March 26, 2019 (attached as Exhibit 6). And while Bayer indicated that "we are more interested in pre-January 2005 documents" with respect to Avelox, it made clear that "we again are not waiving our right to request documents from after that date at some time." *See id*.

In sum, the FDA has more than complied with its obligations under the Federal Rules of Civil Procedure. The FDA conducted a search of documents from several components within FDA for documents responsive to Bayer's requests and repeatedly informed Bayer that it "did not locate any records responsive to FDA Request Nos. 5, 9-13, and 14-18." *See* Exhibit 5 at 1 (November 20, 2019 Email from L. DiPaola to N. Chandran). Bayer's effort to extract an affirmative statement from FDA about whether "it had ever participated in CMS's decision to approve or deny payment for a claim on the basis of an alleged kickback or off-label use" is not a proper use of its subpoena for documents. The FDA indicated that it found no responsive documents for certain requests. Nothing further is required. Accordingly, the Government respectfully requests that Bayer's motion to compel be denied and its subpoena to FDA be quashed in its entirety.

[8] The majority of records in FDA's possession are submissions from Bayer, which Bayer itself is required to maintain.

C. Bayer's Vastly Overbroad and Unduly Burdensome Subpoena to DOJ Seeks Information That is Irrelevant and Disproportional to the Needs of the Case and Should be Quashed

Bayer's subpoena to DOJ contained nineteen broad and burdensome requests, none of which are remotely relevant to the materiality inquiry. *See, e.g.*, Rule 45 Subpoena to DOJ dated March 13, 2019 ("DOJ Subpoena") (Exhibit B to Bayer Mot. Compel). As with FDA, Bayer is well aware that DOJ does not make payment decisions on Medicare claims submitted to CMS. Not a single request to DOJ has any bearing on the Government action factor. Nor has Bayer explained how any of its requests to DOJ have any bearing on any aspect of the materiality issue.

Many of the requests sought information concerning "DOJ's review" or "DOJ's determinations" regarding its investigation of Bayer (DOJ Subpoena Request Nos. 1-6); DOJ's positions regarding the AKS or Medicare's "reasonable and necessary" requirement (DOJ Subpoena Request Nos. 7-8); and communications between DOJ and CMS regarding processes for paying or denying claims, or enforcement actions related to the Medicare Program (DOJ Subpoena Request Nos. 9-13).

By letter dated March 26, 2019, DOJ submitted timely and written objections to Bayer pursuant to Fed. R. Civ. P. 45(d)(2)(B). *See* Letter from P. Mussenden (DOJ) to J. Cohn dated March 26, 2019 (attached as Exhibit 7). DOJ explained that because it was not the government agency that made the payment decisions at issue in the case, Bayer's discovery was misdirected. *See id*. at 2. To the extent Bayer sought a "better understanding of DOJ's view" of materiality, DOJ explained that those views were set forth in the briefs that it had filed in the case. *See id*. DOJ further objected that Bayer's requests were overly broad and failed to describe with particularity the types of information requested; were overbroad and unduly burdensome as to the time period; sought information that was in Bayer's possession or publicly available; and sought information that was privileged. *See id*. at 3-5. Bayer has yet to articulate a cogent explanation for why the views of DOJ, which does not administer federal health care programs, have any bearing on the issues in this case.

As Bayer concedes, it asked DOJ for, and DOJ proposed, a representation regarding the absence of DOJ's role in the payment of Medicare claims in exchange for its withdrawal of its subpoena. *See* Exhibit P to Bayer Mot. Compel at 1-2. But despite receiving the proposed representation, Bayer refused to withdraw its subpoena, defeating the purpose of further discussion or negotiation of such a representation. Bayer further claims that DOJ failed to address the "date on which it had knowledge of the relator's allegations in this case." Bayer Mot. Compel at 9. But Bayer obviously knows the date the *qui tam* Complaint was filed in the case. Moreover, as explained, the Government's "knowledge of the relator's allegations in this case" is irrelevant to Government action, which requires "actual knowledge" of violations, not mere notice of allegations. *See supra* at 8-9. Accordingly, the Government respectfully requests that Bayer's motion to compel be denied and its subpoena to DOJ be quashed in its entirety.

D. Bayer's Vastly Overbroad and Unduly Burdensome Subpoenas to DOD and the VA Seek Information Irrelevant to Medicare's Reasonable and Necessary Requirement and Should be Quashed

Bayer has served two almost identical subpoenas on the Department of Defense (DOD) and the Department of Veterans Affairs (VA), even though there are no DOD (TRICARE) or VA healthcare program claims at issue in this litigation. *See* Rule 45 Subpoena to DOD dated September 24, 2019 ("DOD Subpoena") (Exhibit D to Bayer Mot. Compel); Rule 45 Subpoena to VA dated September 24, 2019 ("VA Subpoena") (Exhibit E to Bayer Mot. Compel) (collectively "DOD/VA Subpoena").

Bayer's subpoenas to each agency contained seventeen separate requests, seeking all documents relating to DOD's and VA's review and approval of Trasylol or Avelox at any DOD and VA facility. (DOD/VA Subpoenas Request Nos. 1-4); and DOD and VA policies regarding off-label use, authority to deny, review or audit any claim, or communications with CMS. (DOD/VA Subpoenas Request No. 5, 15-17).

DOD and the VA separately submitted timely written objections to Bayer's respective subpoenas, explaining that they did not have any claims at issue in the case, and objecting on several other grounds. *See* Letter from M. Jacobs (DOD) to J. Cohn dated October 11, 2019 (attached as Exhibit 8); Letter from S. Cooper (VA) to J. Cohn dated October 10, 2019 (attached as Exhibit 9).

Bayer attempts to justify its subpoenas to DOD and the VA by arguing that "if government physicians used Trasylol off-label in the same ways at issue in this case, that would support Bayer's argument that such off-label use was reasonable and necessary." Bayer Mot. Compel at 4, 10-11. These subpoenas are yet another example of how Bayer misunderstands the materiality inquiry under *Escobar* and the wide net it has cast with its fishing expedition for irrelevant documents.

As noted above, there are no DOD or VA claims remaining at issue in this case. Bayer's subpoenas to DOD and VA therefore seek information that has no bearing on the question of CMS's payment decision on the Medicare claims at issue in this case. The DOD and VA play no role in CMS's automated payment of claims, and Medicare has its own coverage and payment rules regarding the "reasonable and necessary" requirement that are separate and apart from the DOD and VA payment rules. Therefore, DOD's and VA's payment practices have no relevance as to whether Bayer violated Medicare's "reasonable and necessary" requirement as applied to the off-label promotion of its drugs.

Moreover, Bayer merely speculates about off-label usage of Trasylol by DOD and VA physicians. But, Bayer fails to explain how any such speculated off-label usage within DOD and VA has any bearing on the "reasonableness and necessity" of those uses under Medicare. Indeed, a more plausible explanation for any such off-label usage (if it were to exist) is that it was the result of Bayer's allegedly illegal off-label promotion campaign rather than evidence that such uses are reasonable and necessary under Medicare. Finally, there is no reason to think that usage at DOD or VA hospitals has any more bearing on CMS payment decisions than usage of the drug at the

thousands of other private and public hospitals in the United States. Yet, we are not aware of Bayer seeking the same level of burdensome discovery from its hospital customers even though its reason for seeking the DOD or VA discovery would apply equally to such institutions.

Bayer's subpoenas to DOD and VA seek information that is irrelevant to the materiality issue or any of its defenses in this case. Accordingly, the Government respectfully requests that Bayer's motion to compel be denied and Bayer's subpoenas to DOD and VA be quashed in their entirety.

II. Bayer's Vastly Overbroad and Unduly Burdensome Subpoenas Have No Relevance to the Materiality Inquiry Under Escobar

Despite the documented and extensive record of the Government's efforts, Bayer attempts to justify its vastly overbroad and unduly burdensome subpoenas on several grounds, all of which are meritless and which underscore the irrelevance of its discovery.

A. Whether CMS Has "Ever Denied Payment" is Irrelevant and Ignores Actual Knowledge Required to Assess Government Action

First, Bayer argues that it "sought to learn whether the Government has ever denied payment based on alleged violations of the AKS or off-label rules." Bayer Mot. Compel at 3, 6. But, the relevant inquiry for purposes of assessing Government action is not whether the "Government has ever denied payment based on alleged violations of the AKS or off-label rules" because this argument omits the critical element of "actual knowledge" emphasized by *Escobar* and this Court's April 23, 2019 ruling. Rather, to the extent Government action is relevant, the question is what the Government would have done if it had "actual knowledge that certain requirements were violated." *Bayer*, 376 F. Supp. 3d at 415 (quoting *Escobar*, 136 S. Ct. at 2003-04).

Kickbacks are a pernicious problem in federal healthcare programs and often difficult to identify. *See United States ex rel. Greenfield v. Medco Health Solutions, Inc.*, 880 F.3d 89, 96 (3d Cir. 2018) (noting that Congress intended to strengthen the AKS because fraud and abuse is difficult to identify, prove, and correct). CMS processes and pays hundreds of millions of Medicare claims each year through an automated claims submission process. Kickbacks cannot be detected by the automated claims submission process before a claim is paid, absent a self-disclosure. It is highly unlikely, however, that an entity paying a kickback would self-disclose its violation of the AKS on the face of the claim. As this Court recognized, "Bayer was able to perpetrate the alleged fraud precisely because the DRG system disguised the use of kickback tainted claims from Government payers." *See Bayer*, 376 F. Supp. 3d at 413, 416 (noting that "all fraud is disguised -- until it is not."). Thus, Bayer's discovery into whether the Government has "ever denied payment" reveals nothing about the importance the government places on compliance with these requirements unless at the time of payment the Government had "actual knowledge that

certain requirements were violated."[9] Bayer has not even attempted to explain why it thinks that the Government knew of its fraud (which Bayer itself still denies occurred) at the time that it processed the claims for payment at issue in this case.

Bayer contends that the central issue is "whether 'the Government consistently refuses to pay claims in the mine run of cases based on non-compliance with the AKS' or off-label uses." Bayer Mot. Compel at 6. But Bayer omits key language from the Court's April 23, 2019 ruling. The Court's ruling comes directly from *Escobar* that "proof of materiality *can include, but is not necessarily limited to*, evidence that *the defendant* knows that the Government consistently refuses to pay claims in the mine run of cases based on noncompliance with the particular statutory, regulatory, or contractual requirement." *Id*. (emphasis added). That "proof of materiality can include, but is not necessarily limited to, evidence" about what "the defendant knows" confirms that such evidence relates to *Bayer's knowledge* and is just one of several non-dispositive factors. Insofar as Bayer's knowledge is concerned, Bayer knows full-well that the "reasonable and necessary" requirement plays a central role in the coverage and payment of Medicare claims and that the Government vigorously enforces the AKS, all of which are a matter of public record. *See e.g.*, https://www.justice.gov/archive/opa/pr/2008/November/08-civ-1050.html.

B. Bayer Refuses Electronic Claims Data, a More Convenient, Less Burdensome, and Less Expensive Form of Discovery, Yet Moves to Compel the Production of More Burdensome and Irrelevant Information

Next, Bayer argues that its discovery seeks information relating to "the Government's 'actual' or 'likely' conduct regarding the payment of claims." Bayer Mot. Compel at 6. Bayer's argument is baseless. If Bayer were genuinely interested in information regarding the Government's "conduct regarding the payment of claims," it would submit a targeted request for electronic claims data from the National Claims History Database. In fact, CMS repeatedly offered Bayer the option of producing electronic claims data in response to an appropriately framed request and upon payment of the normal processing charge. Bayer refused. CMS received such a request from the relator and invited Bayer to collaborate on a joint request and an equitable sharing of the costs. Bayer again refused. Instead, Bayer has moved to compel the production of vast amounts irrelevant information disconnected from the actual "payment of claims" or from agencies that have no role in the payment of Medicare claims, while spurning actual electronic Medicare claims data that is far "more convenient, less burdensome, or less expensive" to produce. As this Court observed in its March 26, 2020 Order with respect to the aged paper records, Bayer has "failed to

[9] Although it is highly unlikely that CMS will know of actual AKS violations at the time of payment, the Government routinely takes action to recover overpayments whether through error or fraud. Furthermore, the Government frequently pursues False Claims Act (FCA) cases arising from violations of the AKS or the "reasonable and necessary" requirement as it relates to off-label uses of drugs, after payment, all of which are a matter of public record and available to Bayer through basic internet research. Examples of the Government's enforcement of the AKS can be found at the following link on the DOJ website available to the public. https://www.justice.gov/news?sort=field_pr_date&order=desc&keys=kickback&items_per_page=25&f%5B0%5D=type%3Apress_release. Examples of the Government's enforcement of the "reasonable and necessary" requirement as it applies to off-label uses of drugs can be found at the following link on the DOJ website also available to the public. https://www.justice.gov/news?keys=off-label&items_per_page=25.

explain why the information in the National Claims History database is inadequate and why the paper records themselves must be provided." Order at 11. The Court's observation is particularly apt with respect to the irrelevant discovery, the production of which Bayer now seeks to compel. CMS remains willing to provide Bayer with electronic claims data on the same terms that it has agreed to provide such data to the relator – identification of hospitals and DRG codes for a defined time period and upon payment of the normal processing charge for such information.

C. The Government's Awareness of Allegations in a *Qui Tam* Complaint is Irrelevant Under Escobar and This Court's Ruling

Next, Bayer argues that "the Government's actual knowledge is relevant to a potential defense" because "the Government continued to pay Trasylol claims for years even after it learned about all of the *allegations in this case in 2005* (if not before) when Relator filed her complaint." *See* Bayer Mot. Compel at 3-4 (emphasis added); *id*. at 8 ("Bayer also requested documents regarding the Government's 'actual knowledge' of the allegations in this case"). Not only does Bayer fail to explain why its subpoenas seek information well before the relator filed her complaint (1996 through July 2005), but even after she filed her complaint, at most, the Government would have acquired notice of "allegations" as opposed to "actual knowledge that [the AKS and the "reasonable and necessary"] requirements were violated."

Several courts that have confronted this argument have flatly rejected it. It is now established that "actual knowledge that certain requirements were violated," as required under *Escobar* is not the same as awareness of *allegations* of violations. *See United States ex rel. Escobar v. Universal Health Servs., Inc.*, 842 F.3d 103, 112 (1st Cir. 2016) ("mere awareness of allegations concerning non-compliance is different from knowledge of actual non-compliance"); *United States ex rel. Rahimi v. Rite Aid Corp.*, 2019 WL 1426333, at *8 (E.D. Mich Mar. 30, 2019) ("Rite Aid's argument conflates 'actual knowledge that certain requirements were violated' with actual knowledge of allegations that certain requirements were violated"); *United States ex rel. Brown v. Pfizer, Inc.*, 2017 WL 1344365, at *11 (E.D.Pa April 17, 2017) ("mere knowledge of allegations regarding noncompliance is insufficient to prove actual knowledge of noncompliance").

Moreover, that the Medicare program continued to pay claims after relator filed her *qui tam* action says nothing about the importance or materiality of the AKS or the "reasonable and necessary" requirement. As explained by one Court when rejecting a similar argument:

> This Court doubts that the hospital industry would warmly welcome a rule that required the Government to cut off hospital funding whenever a *qui tam* action is filed or forfeit its right to seek reimbursement. The Government does not enjoy the luxury of refusing to reimburse health care claims the moment it suspects there may be wrongdoing. To this day, defendants claim they did not have the requisite scienter to violate the FCA.

United States ex rel. Longo v. Wheeling Hosp. 2019 WL 4478843, at *7 (N.D. W. Va. Sept. 18, 2019). Similarly, in this case, Bayer surely would not welcome a rule that would require the

Government to cut off funding for its drugs under federal healthcare programs based upon a mere allegation of fraud. Indeed, to this day, Bayer vigorously contests that it violated the AKS or the "reasonable and necessary" requirement as applied to the off-label usage of drugs.

Finally, even when the government has actual knowledge of the defendant's wrongful conduct and continues to pay claims, such action does not necessarily undermine materiality because there are many important public health and safety reasons why the government might continue to pay claims. The government is charged with ensuring the delivery of health care to many millions of Americans enrolled in Medicare, Medicaid and other health insurance programs. While the government may properly halt payments in the face of fraudulent conduct, such decisions are necessarily tempered by the need to ensure adequate access to health care, including considerations such as the unavailability of similar services from different providers.

D. Bayer's Request for Information About Government Employee Attendance at Conferences Has No Bearing on Whether Bayer Paid Kickbacks in Violation of the Anti-Kickback Statute

Bayer argues that its discovery as to whether Government employees were permitted to attend conferences would "undercut Relator's claim that Bayer's conferences constituted kickbacks." Bayer Mot. Compel at 4. Bayer also contends that "[i]t would also support a defense based on the Government's actual knowledge." *Id*. at 8, 10-11. Once again, Bayer fails to explain how this information has any bearing on either the materiality of AKS violations or the Government's knowledge of Bayer's kickbacks.

Bayer allegedly caused the submission of false claims involving the drugs Trasylol and Avelox to the Medicare program by paying kickbacks to physicians and other healthcare professionals in violation of the AKS. It is difficult to see how Government employee attendance at any conferences for any purpose has any bearing or logical connection whatsoever to whether Bayer violated the AKS by paying kickbacks to physicians to induce those physicians to prescribe Trasylol or Avelox.

E. Bayer's Arguments Regarding Burden and Proportionality

Finally, Bayer's argument that the Government has no burden or proportionality defense is meritless. *See* Bayer Mot. Compel at 7, 8, 10. Bayer makes this argument in apparent recognition that its subpoenas are facially overbroad, unduly burdensome, and seek vast amounts of irrelevant information. Bayer has compounded the burden with vague and, and in certain instances, incomprehensible requests that lack particularity or focus as to any specific category of documents sought. Bayer's motion to compel thus fails to identify with any specificity any discrete category of relevant documents that the Government has not produced.

The Federal Rules impose a mandatory obligation on a party to propound discovery relevant to the party's defense and "proportional to the needs of the case." It does not authorize, much less justify, fishing expeditions for irrelevant information of the kind Bayer has propounded in this case. In a direct reference to the Government's authority to dismiss the relator's False

Claims Act case under 31 U.S.C. § 3730(c)(2)(A), Bayer once again complains that "the Government has ultimate control over this litigation and has done nothing to limit the scope of this case." Bayer Mot. Compel at 7.

Regardless of whether the Government exercised that authority, Bayer had an independent and mandatory duty pursuant to Fed. R. Civ. P. 45(d)(1) to take reasonable steps to avoid undue burden and expense on the Government. Bayer failed to do so here. As previously explained, *see* ECF No. 368, at 4-5; ECF No. 373, at 7, Bayer's efforts to extract an inaccurate and irrelevant stipulation from the Government for its own litigation advantage do not qualify as taking "reasonable steps to avoid imposing undue burden."

CONCLUSION

For the foregoing reasons, the United States respectfully requests that the Court deny Bayer's motion to compel and quash its subpoenas to CMS, FDA, DOJ, VA and DOD in their entirety.

Respectfully submitted,

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